Remarks

Claims 1-16 are pending in this application.

I. Response to Rejection under 35 U.S.C. § 102

A. Legal Foundation for Examination under 35 U.S.C. § 102

Before discussing rejections based upon 35 U.S.C. § 102, it is believed proper to state that to sustain a rejection under § 102 the Patent and Trademark Office must abide by the following statement of the law.

> Under 35 U.S.C. § 102, anticipation requires that each and every element of the claimed invention be disclosed in a prior art reference. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1554, 220 USPQ 303, 313 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). In addition, the prior art reference must be enabling, thus placing the allegedly disclosed matter in the possession of the public. *In re Brown*, 329 F.2d 1006, 1011, 141 USPQ 245, 249 (CCPA 1964).

Akzo N.V. v. U.S. Int'l Trade Comm'n, 1 U.S.P.Q.2d 1241, 1245 (Fed. Cir. 1986).

B. Factual and Legal Analysis

Claim 6 was rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 6,245,753 ("Byun '753").

Byun '753 discloses heparin bound to a hydrophobic material. Contrary to the allegation of the Office Action, Byun '753 does not disclose an antithrombogenic heparinized polymer comprising a macromolecule, a hydrophobic material, and heparin bound together by covalent bonds. The Office Action referred to the abstract;

col. 2, lines 33-44; col. 4, line 66, to col. 5, line 2; and claim 11 as supposedly making the alleged disclosure. Each of these sections of Byun '753 will be examined in more detail below.

The abstract of Byun '753 describes heparin derivatives synthesized by conjugation to bile acids or to sterols or to alkanoic acids. Thus, the abstract discloses heparin conjugated to a hydrophobic material, but fails to disclose a an antithrombogenic heparinized polymer layer comprising a macromolecule, a hydrophobic material, and heparin bound together by covalent bonds.

Col. 2, lines 33-44, of Byun '753 discloses a composition comprising a polysaccharide covalently bonded to a hydrophobic agent. Thus, this passage discloses heparin conjugated to a hydrophobic material or a macromolecule conjugated to a hydrophobic material, but fails to disclose an antithrombogenic heparinized polymer layer comprising a macromolecule, a hydrophobic material, and heparin bound together by covalent bonds.

Col. 4, line 66, to col. 5, line 2, of Byun '753 discloses mixing a hydrophobic heparin derivative, i.e., heparin conjugated to a hydrophobic material, with a carrier, and then coating the surface of a medical device with the mixture. There is no disclosure of covalent bonds being formed between the heparin-hydrophobic material conjugate, and, moreover, there is no

enabling disclosure in Byun '753 of how to form covalent bonds between the heparin-hydrophobic material conjugate and a carrier. Thus, this passage discloses coating the surface of a medical device with a mixture of a carrier and a conjugate formed by covalent bonding of heparin to a hydrophobic material, but fails to disclose coating a medical device with an antithrombogenic heparinized polymer layer comprising a macromolecule, a hydrophobic material, and heparin bound together by covalent bonds.

Claim 11 of Byun '753 discloses a pharmaceutical composition comprising (a) a pharmaceutically effective amount of a composition of matter comprising a polysaccharide covalently bonded to a hydrophobic agent, and (b) a pharmaceutically acceptable carrier, wherein the carrier is a polymeric matrix selected from the group consisting of poly(ethylene oxide)-poly(ε-caprolactone) copolymers, polyurethane polymers, silicone polymers, ethylene vinyl acetate polymers, hydrogels, collagen, gelatin, and mixtures thereof. The nature of the relationship between (a) the composition comprising the polysaccharide covalently bonded to the hydrophobic agent and (b) the carrier is not explicitly stated in claims 8-11. The specification provides some guidance, however. For example, at column 4, lines 66-67, it is stated that the hydrophobic heparin derivative, i.e., a species of polysaccharide covalently bonded to a hydrophobic agent, is typically mixed with a carrier. This is exemplified in

Example 8, wherein a hydrophobic heparin derivative was mixed with a PEO/PCL multiblock copolymer. Column 8, lines 43-52. Therefore, claim 11 fails to disclose coating a medical device with an antithrombogenic heparinized polymer layer comprising a macromolecule, a hydrophobic material, and heparin bound together by covalent bonds.

Therefore, Byun '753 fails to disclose each and every element of claim 6. More particularly, Byun '753 fails to disclose a composition wherein heparin, a hydrophobic material, and a macromolecule are covalently bonded to each other. For this reason, Byun '753 fails to anticipate claim 6 under 35 U.S.C. § 102(b). Hence the rejection is unfounded and should be withdrawn.

II. Response to Rejections under 35 U.S.C. § 103(a)

A. Legal Foundation for Examination under 35 U.S.C. § 103(a)

Before responding directly to the issues raised by the Office Action under Section 103, the legal foundation for sustaining such a rejection again will be reviewed. Briefly, an applicant for a patent is entitled to the patent unless the application fails to meet the requirements established by law. 35 U.S.C. §§ 101, 102, 103, 112. It is the USPTO's duty to issue a patent or establish that the applicant is not entitled to a patent under the law. *In re Warner*, 154 USPQ 173, 177 (CCPA 1967), *cert. denied*, 389 U.S. 1057 (1968). Thus, the initial

burden is on the USPTO to establish a *prima facie* case of obviousness. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). If no *prima facie* case of obviousness is established, then a rejection under Section 103 cannot properly be sustained. *In re Oetiker*, 24 U.S.P.Q.2d 1443 (Fed. Cir. 1992). If the USPTO establishes a *prima facie* case of obviousness, then the burden of production shifts to the applicant to provide appropriate rebuttal, although the burden of persuasion always remains with the USPTO. *Id.* Such rebuttal may include arguments, amendments, and/or presentation of objective indicia of nonobviousness. However, such objective indicia are always relevant to a determination of nonobviousness whether or not a *prima facie* case of obviousness has been established. *Stratoflex Inc. v. Aeroquip Corp.*, 218 U.S.P.Q. 871, 879 (Fed. Cir. 1987). To establish a *prima facie* case of obviousness, the USPTO must show all of the limitations of the claimed invention in the prior art. *In re Ehrreich*, 200 U.S.P.Q. 504, 509-11 (C.C.P.A. 1979). The subject matter of the invention must be considered as a whole and through the eyes of a hypothetical person of ordinary skill, not expert skill, in the relevant art at the time the invention was made. *Connell v. Sears, Roebuck & Co.*, 220 U.S.P.Q. 193, 199 (Fed. Cir. 1983). References must also be considered as a whole, including subject matter that teaches away from the invention as well as subject matter that suggests the invention, and not for their isolated teachings.

Ashland Oil, Inc. v. Delta Resins & Refractories, Inc., 227 U.S.P.Q. 657, 669 (Fed. Cir. 1985). References may be combined if there would be a "reason to combine" them. *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1740-41, 1742 (2007). That is, "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art" because "inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." *Id.* at 1741. In nonobviousness analysis, one must "guard against slipping into the use of hindsight" and "resist the temptation to read into the prior art the teachings of the invention in issue." *Graham*, 383 U.S. at 36, 148 USPQ at 474; *KSR*, 127 S. Ct. at 1742. Finally, all the facts in evidence are evaluated, and patentability is determined on the totality of the record. *In re Corkill*, 226 USPQ 1005, 1008 (Fed. Cir. 1985). Factual determinations made by the USPTO must be based on a preponderance of the evidence, and legal conclusions must be correct. *In re Caveny*, 226 USPQ 1, 3 (Fed. Cir. 1985).

Pursuant to established legal authority, patentability under 35 U.S.C. § 103 requires a four-step factual analysis, which involves (1) determining the scope and content of the prior art, (2) ascertaining the differences between the prior art and the claimed inventions, (3) resolving the level of ordinary skill in

the pertinent art, and (4) utilizing the objective evidence of nonobviousness that may have been presented. *Graham v. John Deere Co.*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966). After all of these factors have been considered, the ultimate legal conclusion on the issue of obviousness must be reached. With the above background in mind the rejections under 35 U.S.C. § 103 will be discussed.

B. Factual and Legal Analysis

1. Response to Rejection of Claims 1-12 and 14-16 over U.S. Patent No. 5,879,697 (Ding) in view of U.S. Patent No. 6,251,142 (Bernacca) and U.S. Patent No. 6,245,753 (Byun '753)

Claims 1-12 and 14-16 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 5,879,697 (Ding) in view of U.S. Patent No. 6,251,142 (Bernacca) and Byun '753.

Ding discloses drug-releasing coatings for medical devices. The abstract states:

> [T]he coating comprises at least two layers: an outer layer containing at least one drug-ionic surfactant complex overlying a reservoir layer containing a polymer and the drug which is substantially free of an ionic surfactant. Upon exposure to the body tissue of a medical device covered with such coating, the ionically bound drug in the outer layer is released into body fluid or tissue. Following release of such bound drug, the ionic surfactant binding sites in the outer layer are left vacant. To maintain the pharmacological activity after delivery of the ionically bound drug, additional amounts of the drug are embedded or incorporated in the reservoir layer in a manner which allows the drug, which is substantially free of ionic surfactants, to complex with the vacant binding sites of the ionic surfactant of the outer layer.

See also, column 2, line 62, to column 3, line 16. Ding further states:

> The complexes formed according to the present invention will result primarily from ionic interactions between negatively charged drugs and positively charged surfactants or positively charged drugs and negatively charged surfactants. However, certain secondary forces may also exist to contribute to the formation or maintenance of the complexes, such as hydrogen bonding, dipole-dipole interaction, charge-dipole interaction . . . .

Column 4, lines 8-15. Thus, Ding discloses non-covalent bonds between a charged drug and an oppositely charged surfactant. Ding also discloses mixtures of the drug and a polymer. Column 4, lines 24-37. The drug and polymer are not bonded to each other, because bonding of the drug to the polymer would prevent the drug from being released, which is a property of Ding's invention. Column 3, lines 13-17. Therefore, Ding fails to disclose covalent bonds between heparin and anything.

Bernacca discloses an implantation device in which at least a portion of the surface of the device is coated with a receptor capable of binding selectively with a ligand formed by combining an active principle (i.e., a drug or a diagnostic; col. 4, lines 60-63) with a substance capable of binding specifically to the receptor. Col. 3, lines 1-6. Preferred receptors are disclosed at col. 3, lines 18-20. Binding pairs are disclosed at col. 4, lines 18-22. Biotinylated heparin is disclosed as an example of a ligand. Col. 6, lines 45-49. Thus, Bernacca discloses what is presumably a covalently bonded ligand, i.e., heparin covalently

bonded to biotin (a receptor-binding molecule), and Bernacca discloses releasable, non-covalent bonding between the ligand and a receptor.

The disclosure of Byun '753 was reviewed above, and is incorporated herein by reference. Briefly, Byun '753 discloses heparin covalently bonded to a hydrophobic material, and fails to disclose or suggest heparin, a hydrophobic material, and a macromolecule covalently bonded to each other.

Therefore, Ding, Bernacca, and Byun '753, alone or in combination, fail to disclose or suggest a hydrophobic heparinized polymer comprising a macromolecule, a hydrophobic material, and heparin bound together by covalent bonds. Therefore, this combination of references fails to disclose each and every limitation of the presently claimed invention. It is not clear what the combination of Ding, Bernacca, and Byun '753 would suggest to a person of ordinary skill in the art, but it is clear that it is not the presently claimed invention. Therefore, a *prima facie* case of obviousness has not been established with respect to any of claims 1-12 and 14-16.

Further, the Office Action failed to demonstrate that Ding, Bernacca, and Byun '753 were considered in their entireties, as is required under applicable law. The Office Action failed to correctly determine the scope and content of the prior art and also failed to correctly determine the differences between the claimed invention and the prior art, as are required under

Graham. Moreover, the Office Action failed to establish the level of skill of a person of ordinary skill in the art. For the reason that the Office Action failed to follow the mandates of *Graham*, a *prima facie* case of obviousness was not established.

It seems apparent that the Office Action attempted to pick some teachings of the cited references, ignoring others, after first having read Applicants' disclosure and using it as a road map in an attempt to reconstruct Applicants' invention from the disclosures of the prior art. This is impermissible hindsight analysis. For this reason, as well, a *prima facie* case of obviousness was not established.

Therefore, withdrawal of the rejection of claims 1-12 and 14-16 over Ding, Bernacca, and Byun '753 is respectfully requested.

2. Response to Rejection of Claims 1-16 over U.S. Patent No. 5,879,697 (Ding) in view of U.S. Patent No. 6,251,142 (Bernacca) and U.S. Patent No. 7,129,224 (Byun '224)

Claims 1-16 were also rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Ding in view of Bernacca and U.S. Patent No. 7,129,224 ("Byun '224").

The disclosures of Ding and Bernacca were reviewed above, and those reviews are incorporated herein by reference.

Byun '224 discloses subject matter developed by another person, which Applicants believe qualifies as prior art only under Section 102(e). At the time the claimed invention was

made, the subject matter of Byun '224 and the claimed invention were owned by the same person or were subject to an obligation of assignment to the same person. Therefore, Applicants respectfully submit that the subject matter of Byun '224 shall not preclude patentability under Section 103 due to the provisions of Section 103(c)(1).

For this reason, Applicants respectfully request withdrawal of the rejection of claims 1-16 under 35 U.S.C. § 103(a) over the combination of Ding, Bernacca, and Byun '224.

C. Conclusion

In view of the above, withdrawal of the grounds of rejection under Section 103(a) is respectfully requested.

III. Summary and Conclusion

Should the Examiner deem it advisable to conduct a telephone interview for any reason, the undersigned attorney would be most agreeable to receiving a telephone call to expedite the prosecution of the application.

For the reasons given above, Applicants respectfully request reconsideration and allowance of Claims 1-16 and passage of this application to issue.

DATED this 20th day of June, 2008.

Respectfully submitted,

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